

AD_____

Award Number: W81XWH-12-1-0360

TITLE: The Runners And Injury Longitudinal Study: Injury Recovery Supplement
(TRAILS_IR)

PRINCIPAL INVESTIGATOR: Stephen P. Messier, Ph.D.

CONTRACTING ORGANIZATION: Wake Forest University
Winston-Salem, NC 27109

REPORT DATE: August 2013

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for Public Release;
Distribution Unlimited

The views, opinions and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation.

REPORT DOCUMENTATION PAGE				<i>Form Approved</i> OMB No. 0704-0188	
Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing this collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Department of Defense, Washington Headquarters Services, Directorate for Information Operations and Reports (0704-0188), 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302. Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number. PLEASE DO NOT RETURN YOUR FORM TO THE ABOVE ADDRESS.					
1. REPORT DATE August 2013		2. REPORT TYPE Annual		3. DATES COVERED 15 August 2012 – 14 July 2013	
4. TITLE AND SUBTITLE The Runners And Injury Longitudinal Study: Injury Recovery Supplement (TRAILS_IR)				5a. CONTRACT NUMBER	
				5b. GRANT NUMBER W81XWH-12-1-0360	
				5c. PROGRAM ELEMENT NUMBER	
6. AUTHOR(S) Stephen P. Messier, Ph.D., Edward Ip, Ph.D., Paul DeVita, Ph.D., Shannon Mihalko, Ph.D., Wayne Cannon, P.T., ATC; Joseph F. Seay, Ph.D., David F. Martin, M.D. E-Mail: messier@wfu.edu				5d. PROJECT NUMBER	
				5e. TASK NUMBER	
				5f. WORK UNIT NUMBER	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) Wake Forest University Winston-Salem, NC 27109				8. PERFORMING ORGANIZATION REPORT NUMBER	
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012				10. SPONSOR/MONITOR'S ACRONYM(S)	
				11. SPONSOR/MONITOR'S REPORT NUMBER(S)	
12. DISTRIBUTION / AVAILABILITY STATEMENT Approved for Public Release; Distribution Unlimited					
13. SUPPLEMENTARY NOTES					
14. ABSTRACT The Runners And Injury Longitudinal Study (TRAILS) is an ongoing two year prospective observational study funded through the USAMRMC Broad Agency Announcement mechanism (W81XWH-10-1-0455). It is designed to compare runners who sustain an overuse running injury during the observational period to those who remain injury-free on a discrete set of behavioral, physiological, and biomechanical variables. The proposed supplement will focus on injury recovery (TRAILS: Injury Recovery Supplement). It will enhance the parent project (TRAILS) by determining if the severity of an overuse running injury affects the duration of recovery (i.e., return to pre-injury weekly mileage), the magnitude of chronic changes in strength and gait mechanics that could be risk factors for early-onset osteoarthritis and mobility disability, and the association of injury severity with psychological well-being and pain. We plan to add 100 non-injured runners to our cohort of 200 runners that are enrolled in the parent grant (TRAILS). This will enhance the power of our aims for TRAILS and increase the number of potential injured runners to follow in our proposed Injury Recovery Supplement from 90 to 140. Our primary hypothesis is there will be significant direct relationships between the severity of overuse running injury and the magnitude of the change in strength, lower extremity joint loads, and psychological well-being from pre-injury levels despite a return to pre-injury training mileage. Determining whether the effects of a significant overuse injury are evident after the symptoms subside has important potential public health implications. It will inform whether a return to pre-injury activity is appropriate, if further treatment is required, and whether the injured runner exhibits chronic biomechanical and strength abnormalities that increase the risk of lower extremity osteoarthritis, and disability later in life. Combined, TRAILS and the TRAILS: Injury Recovery Supplement will (1) inform as to what variables distinguish runners who sustain an overuse running injury from those who remain injury free, (2) develop statistical models that integrate biomechanical, behavioral, and psychological risk factors for injury, (3) determine the length of time required for recovery from mild, moderate, and severe overuse injuries, (4) document rehabilitation methods used during recovery, (5) identify potential chronic deficits in muscle strength and gait that persist after regular training mileage has been resumed and thus identify a potential mechanism for long term mobility disability, and (6) examine the influence of injury severity and length of recovery on psychological well-being and pain.					
15. SUBJECT TERMS Running, overuse injury, anterior knee pain, biomechanical, behavioral, physiological					
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT UU	18. NUMBER OF PAGES 13	19a. NAME OF RESPONSIBLE PERSON USAMRMC
a. REPORT U	b. ABSTRACT U	c. THIS PAGE U			19b. TELEPHONE NUMBER (include area code)

Table of Contents

	<u>Page</u>
Introduction.....	5
Body.....	7
Key Research Accomplishments.....	9
Reportable Outcomes.....	10
Conclusion.....	11
References.....	12
Appendices.....	13
Appendix A: “Differences in Running Mechanics and Flexibility Between Runners in Minimalist and Traditional Footwear”.....	14

Introduction

Little is known regarding the length of time required to recover from an overuse injury, defined by a return to pre-injury weekly mileage, and the relationships among the magnitude of injury severity and chronic effects on strength, running mechanics and psychological well-being. Further, there are no data indicating whether improvements in behavioral outcomes during the recovery period are accompanied by a return to pre-injury gait mechanics, muscle strength, and well-being or whether improvements in gait, strength, and well-being lag behind a return to pre-injury training mileage. Permanent changes in gait mechanics and strength could cause chronic overloading of lower extremity joints and surrounding soft tissue resulting in early onset osteoarthritis and mobility disability. For example, post-traumatic osteoarthritis due to meniscal or ACL injury develops 10-20 years earlier than idiopathic or primary osteoarthritis. Whether chronic overuse soft tissue running injuries have similar effects is unknown. Determining whether the effects of a significant overuse injury are evident after the symptoms subside will inform whether a return to pre-injury activity is appropriate, if further treatment is required, and whether the injured runner exhibits chronic biomechanical and strength abnormalities that increase the risk of lower extremity osteoarthritis and disability later in life. Long term declines in psychological well-being could impact subsequent behavior and quality of life. For example, decreased efficacy for maintaining one's running regimen may lead to a longer recovery period or drop-out from activity altogether. Further, an anxious runner may further alter running mechanics and collectively, these psychological and behavioral changes may contribute to decreased quality of life and disability over time.

The proposed Injury Recovery project will enhance the parent grant in the following ways:

1. Increase the sample size from 200 to 300, thereby improving the power of the parent grant to distinguish those who sustain an overuse injury from those who remain injury free.

2. Increase the potential observation period for non-injured runners from 1 to 2 years thereby increasing the number of runners we predict will sustain an injury from 90 to 140.
3. Add pelvis and lower extremity coordination and ankle bone-on-bone force data to the biomechanical analysis as possible risk factors for injury

In addition, the Injury Recovery supplement will add the following novel outcomes:

1. An *injury recovery* component that is missing in the parent grant and in the existing literature
2. Determine if more severe overuse soft tissue injuries result in chronic changes in strength and gait mechanics that could be risk factors for early-onset osteoarthritis and mobility disability.
3. Documentation of rehabilitation methods used during recovery
4. A psychological well-being component to the injury recovery analysis

Currently, we are in the process of recruiting 100 additional runners (85 are enrolled and participating to date) to add to the existing cohort of 184. We are also continually testing recovered runners and runners who have remained injury-free for a period of 18 months in the study to serve as a comparison group.

Body

For the 269 runners enrolled and participating in the parent grant and supplement, compliance with biweekly reporting is 93% (7,652 responses to 8,180 emails sent). There were 100 injuries in the parent grant in the first year of participation (116% of predicted), and an additional 19 runners have been injured in their second year of participation. Currently, there are 17 runners injured in the supplement grant, out of the additional 85 that have been recruited thus far.

Recruitment, testing, and study compliance have been excellent. We plan on meeting our recruitment goal of 100 runners in the next couple of months. We have 85 runners enrolled to date, and the final 15 will be enrolled by the end of September 2013. The use of the internet to update us on their injury and bi-weekly training status has been a complete success. Compliance is 93% to-date in responding to the bi-weekly emails. The injured participants were examined by our study physician in a timely manner, within two weeks of reporting the injury. We surpassed our predicted injury rate of 45%, with a total of 100 runners sustaining an injury in the first year (54%). Fifty-one runners sustained a Grade 1 injury (injury did not impact training/running, maintained full activity), 36 sustained a Grade 2 injury (injury reduced their weekly mileage), and 13 sustained a Grade 3 injury (injury interrupted their running for at least 2 weeks). Fifty-nine percent of the runners injured were male. Of the 108 males in the parent grant, 59 were injured in the first year (55%), and of the 76 females in the study, 41 were injured in the first year (55%). We are bringing the runners back in for Injury Recovery Visits after they have recovered from their Grade 2/3 injuries. We are also bringing the runners back in for testing who have remained injury-free for 18 months in the study, to serve as a control group. To date, 35 runners have recovered and completed the Injury Recovery Visits, and 26 have completed their visits to serve as controls.

Monthly investigator meetings are scheduled to discuss study progress and possible ideas for abstracts, manuscripts, and

presentations. We have had an abstract accepted for the American College of Sports Medicine (ACSM) annual meeting entitled "Differences in Running Mechanics and Flexibility between Runners in Minimalist and Traditional Footwear".

The following are completed deliverables of the study:

- Study planning : Completed

The deliverables still in progress are the following:

- Recruitment: The additional 100 are ongoing. 85 out of 100 have been enrolled. We are continually enrolling participants into the injury recovery study as they recover from their injuries, or have been injury-free for a period of at least 18 months while in the parent grant.
- Baseline testing: Ongoing. 85 have completed to date.
- Injury Recovery testing: Ongoing. 35 have completed injury recovery testing; 26 have completed testing for the control group.
- Injury Rates: new 100 are ongoing. 17 out of 85 have been injured to date
- Follow-up visits: FU6 being currently being conducted

Key Research Accomplishments

- Recruited almost all of our 100 additional participants, on track to reach recruitment goal by October
- Recruitment of recovered runners and control participants has gone well, nearly all participants have been willing to participate in the study and come in for the two follow-up visits
- Baseline testing for the new 100 participants and injury recovery testing is being collected, processed, and double-data entered in a timely fashion
- 100% retention for 6-month follow-up visits to date
- 93% participant compliance to bi-weekly study emails
- Maximizing funding by having volunteers from Wake Forest and other universities aid our paid staff with various study roles
For example: - assist with participant testing, assist with data entry and phone calls
- Monthly investigator meetings to discuss potential baseline papers, abstracts, presentations
- Abstract accepted to a national conference

Reportable Outcomes

We are in the final months of our recruitment period for the additional 100 runners to add to the parent grant. The recruitment is a continual process for the injury recovery visits, as they recover from their injuries or remain injury-free for a period of at least 18 months. We have begun to discuss possible baseline abstracts and manuscripts that will be possible once the entire cohort is enrolled.

All of our collected data are uploaded to our study website that is managed by our biostatistics team. Questionnaires are double-data entered to insure accuracy.

Conclusion

At this time, we are only speculating about potential manuscripts, abstracts, and presentations. We will begin work on this as soon as we have finished recruiting the additional 100 study participants, and as soon as we have finished bringing the recovered runners and control participants in for testing. We have also designed a randomized clinical trial on strength training to prevent musculoskeletal injury in female runners.

References

None to date

Appendices

